

information in the Medication Guide. Use of color in text is one means of highlighting the new or revised information for the patient.

Packaging

Several pharmaceutical manufacturers have examples of appropriate use of color on packaging of prescription drug products to convey important messages from risk management programs. Several examples are well known.

1. Accutane® and Thalomid® are both supplied to pharmacies as solid oral dosage forms inside a carton. In each case, this carton (which is visible to the pharmacist and patient) has a prominent color symbol (including distinctive red) intended to alert pharmacists and patients, at the point of dispensing, to the critical need to avoid use of the drug in pregnant women. In the case of Accutane and Thalomid, this use of color comprises a "visual alert" system to pharmacists and patients.
2. Ziagen®, Trizivir® and Epzicom® all contain abacavir sulfate, a drug substance associated with hypersensitivity reactions in some patients. In order to incorporate a visual "flag" on packaging to remind individuals that all three products contain Ziagen (abacavir), the letters ZI are in red type in all three names on packaging (i.e., **ZI**AGEN, **TRI**ZIVIR, **EP**ZICOM). This use of color comprises a "visual alert" to health care professionals and patients.
3. Controlled substances must be packaged with the federal symbol (e.g., C-III) for a controlled substance on the immediate label and any outer carton used for the product. Although not required by federal regulation (21 CFR 1302), a common current practice is for manufacturers to print this symbol, prominently, in red type on a white background. Use of color in this way comprises another example of a "visual alert" to pharmacists and others regarding the nature of the drug.
4. Finally, there are a number of examples where color and size of letters have been used, along with other approaches, to avoid dispensing errors in association with two proprietary names that may be perceived as "look alike" by some pharmacists. For bottles of Lamictal® Tablets, the last part of the brand name is italicized and printed in red (**Lamictal**) and has a yellow background color highlight for enhanced prominence, to avoid potential confusion between Lamictal and Lamisil. Labels for Epivir® and Epivir-HBV® have the brand name in distinctly different colors to distinguish these products that are used in overlapping patient populations. Historically, for example, Cerebryx and Celebrex were two names that could be confused; use of color in labeling to highlight the unique letters could help pharmacists distinguish these products on the shelf (e.g., **Cerebryx**, **Celebrex**).